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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BOR, HELENE CATHERINE	
ART UNIT	**PAPER NUMBER**
3768	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,452	QIN ET AL.	
	Examiner	Art Unit	
	Helene Brown	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 20 January 2005.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-30 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 20 January 2005 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 04/2205.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Acknowledgement of Preliminary Amendments

2. For the record, acknowledgement is made of the applicant's preliminary amendments to the specification on 05/13/2005 under 37 CFR 1.115. The amendments to the specifications are also acknowledged.

Drawings

3. The drawings are objected to because:

A. Figure 1a & 1b – Confocal point is missing a reference symbol

B. Page 14 2nd Para – Reference 144 is a typo; --14--

C. Figure 1b Element 17 – Re-label as current label is confusing

D. Page 27 2nd Para – Memory referenced as element 22; --27--

E. Figure 3 – Element 410 & 412 not referenced in disclosure.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. The term "approximately" in claim 9, 22 & 25 is a relative term, which renders the claim imprecise and unclear. The term "approximate" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 1- 4, 10-11, & 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kantorovuch'019 (US Patent No. 6,221,019 B1) and further in view of Mourad'176 et al. (US Patent No. 6,875,176 B2).

Claim 1: Kantorovuch'019 teaches ultrasonic system for determining at least one property of bone (Abstract). Also Kantorovuch'019 teaches the use of a processor for determining tissue properties based on the received ultrasound signal (Figure 12, Element 455). Kantorovuch'019 fails to teach confocal transducers. However, Mourad'176 teaches a system for using confocal transducers to receive and transmit the ultrasound for determining tissue properties (Col. 23, Line 20-37). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mourad'176 and Kantorovuch'019 in order to induce an oscillatory radiation force in the target tissue. The oscillatory radiation force produces an emitted acoustic signal from the targeted tissue, which relates to the targeted tissues intrinsic properties (Col. 23, Line 27-33).

Claim 2/1: Kantorovuch'019 teaches the bone sample is a bone in a live human being (Col. 3, Line 55-57).

Claim 3/1: Kantorovuch'019 teaches a system capable of a resolution equal to approximately 0.5 mm (Col. 15, Line 31-33). Kantorovuch'019 fails to teach confocal transducers. However, Mourad'176 teaches a system wherein the confocal point of the transmitting and receiving transducers (Col. 23, Line 20-37). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mourad'176 and Kantorovuch'019 in order to induce an oscillatory radiation force in the target tissue. The oscillatory radiation force produces an emitted acoustic signal from the targeted tissue, which relates to the targeted tissues intrinsic properties (Col. 23, Line 27-33).

Claim 4/1: Kantorovuch'019 teaches a system wherein the transmitting transducer emits ultrasonic signals at a frequency on the order of tens of megahertz (Col. 15, Line 28-30).

Claim 10/1: Kantorovuch'019 teaches a system wherein the at least one ultrasonic parameter determined for the at least one point of the sample are ultrasonic velocity (UV) (Col. 3, Line 52-54) and a measure of ultrasonic attenuation (UA) (Col. 19, Line 1-7).

Claim 11/10/1: Formulas and equations in the abstract are not patentable subject matter (MPEP 2106 Patent Subject Matter Eligibility). The following equation as claimed, $UV_{(x,y,z)} = v_m * w / (w - V_{rn} *\Delta T)$, is not taught by any of the references verbatim. However, Kantorovuch'019 teaches a system wherein ultrasound velocity (Abstract) at the at least one point of the sample is calculated by the processor (Figure 12, Element 455). Kantorovuch'019 teaches using the time delay, the thickness of the

bone and the velocity of the ultrasound in the medium (Col. 13, Line 28-50, Col. 17, Line 63 – Col. 18, Line 33, & Claim 4).

Claim 29: Kantorovuch'019 teaches an ultrasonic system for determining at least one property of materials (Col. 4, Line 60-64). Also, Kantorovuch'019 teaches the use of a processor for determining material properties based on the received ultrasound signal (Figure 12, Element 455). Kantorovuch'019 fails to teach confocal transducers. However, Mourad'176 teaches a system for using confocal transducers to receive and transmit the ultrasound for determining material properties (Col. 23, Line 20-37). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mourad'176 and Kantorovuch'019 in order to induce an oscillatory radiation force in the target material. The oscillatory radiation force produces an emitted acoustic signal from the targeted material, which relates to the targeted material intrinsic properties (Col. 23, Line 27-33).

8. Claim 5-9, 12- 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kantorovuch'019 (US Patent No. 6,221,019 B1), in view of Mourad'176 et al. (US Patent No. 6,875,176 B2) and further in view of Mazess'029 (US Patent No. 5,840,029).

Claim 5/1: Kantorovuch'019 fails to teach the confocal transducers and three dimensional scanning stage. However, Mourad'176 teaches a system for using confocal transducers to receive and transmit the ultrasound for determining material properties (Col. 23, Line 20-37). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mourad'176 and Kantorovuch'019 in order to induce an oscillatory radiation force in the target material. The oscillatory radiation force

produces an emitted acoustic signal from the targeted material, which relates to the targeted material intrinsic properties (Col. 23, Line 27-33). In addition, Mazess'029 teaches using the system for three dimensional grid (x, y, and z plane) and moving the transmitting and receiving transducers in three dimensions (Col. 27, Line 41-44 & Col. 27, Line 61 – Col. 28, Line 6). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order provide the opportunity to use extra data outside the region of interest to ensure that the same region of interest is measure in the patient's heel over a series of measurements made at different times (Col. 28, Line 18-22).

Claim 6/5/1: Kantorovuch'019 fails to teach the confocal transducers. However, Mourad'176 teaches a system for using confocal transducers to receive and transmit the ultrasound for determining material properties (Col. 23, Line 20-37). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mourad'176 and Kantorovuch'019 in order to induce an oscillatory radiation force in the target material. The oscillatory radiation force produces an emitted acoustic signal from the targeted material, which relates to the targeted material intrinsic properties (Col. 23, Line 27-33). Mazess'029 teaches the processor initiating an ultrasonic signal from the transmitting transducers that is transmitted through the bone sample and received by the receiving transducer (Col. 5, Line 40-44). Mazess'029 teaches the processor receiving a signal reflecting one or more measures of the received ultrasonic signal (Col. 5, Line 40-44). Mazess'029 teaches the processor determining at least one ultrasonic parameter for each point in the sample based upon the transmitted and

received ultrasonic signals (Col. 5, Line 50-57). Mazess'029 teaches the processor further determining the at least one bone property at each point of the sample based upon the at least one ultrasonic parameter for the point (Col. 5, Line 50-57). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 so that the system can carry out its operations (Col. 6, Line 1-2)

Claim 7/6/5/1 & 8/6/5/1: Kantorovuch'019 and Mourad'176 fail to teach in detail about the type of scanning the inventions are capable of performing. However, Mazess'029 teaches the three dimensional scanning stage (Col. 27, Line 40-44) wherein it is able of discrete scans, continuous scans and other methods of use that the clinician desires can be selected by a selectable switch (Col. 6, Line 32-67). Mazess'029 thus teaches a functional equivalent to the claimed invention.

Claim 9/5/1: Kantorovuch'019 teaches system wherein each point in the bone sample can have better resolution than 1 mm (Col. 15, Line 29-33) and scanning a small part of the body smaller than 1 mm (Claim 95). Kantorovuch'019 teaches a functional equivalent system capable of the measurements claimed by the applicant.

Claim 12/10/1: Kantorovuch'019 teaches the measure of UA is one selected from the group of broadband ultrasonic attenuation (BUA) (Col. 5, Line 18-27). While Kantorovuch'019 touches on ultrasound attenuation, the focus of the teachings is measuring ultrasound velocity. Kantorovuch'019 and Mourad'176 fail to mention an ultrasound attenuation number (ATT). ATT represents the energy decay attenuation as a function of material density as defined by the applicant on Page 27, 2^{nd} Paragraph.

Mazess'029 goes into detail regarding the applicant defined ATT, although Mazess'029 does not use the term ATT. Mazess'029 states that ultrasound attenuation is dependent on bone mineral density and the integrity being tested (Col. 9, Line 26-54). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order determine the quality of cancellous bone matrix (Col. 9, Line 54-56).

Claim 13/12/10/1: Formulas and equations in the abstract are not patentable subject matter (MPEP 2106 Patent Subject Matter Eligibility). The following equation as claimed, $UAC_{(x,y,z)}$ (f) = 20 Log [(FFT (f_{ref} (t)) / (FFT (f_{bone} (t))], is not taught by any of the references verbatim. However, Mazess'029 teaches a system where the BUA at the at least one point (x,y,z) of the sample is calculated by the processor (Figure 6, Element 38) as the slope of the linear section of the ultrasound attenuation coefficient function, $UAC_{(x,y,z)}$ (f), where $UAC_{(x,y,z)}$ (f) is calculated from the fast fourier transform (FFT) of frequency f (as a function of time) for the received ultrasound signal f_{bone} (t) as passed through the bone sample and a reference (Col. 11, Line 10-16). Ultrasound signal f_{ref} (t) received without the sample positioned between the transducers in accordance with the equation (Col. 9, Line 8-10). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order compare the characteristics of the waveform in frequency response and attenuation through the subject compared to the standard (without the sample) for analysis (Col. 9, Line 18-25). In addition, Mazess'029 teaches using the system for three dimensional grid (x, y, and z plane) (Col. 27, Line 40-44). It would

have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order provide the opportunity to use extra data outside the region of interest to ensure that the same region of interest is measure in the patient's heel over a series of measurements made at different times (Col. 28, Line 18-22).

Claim 14/12/10/1: Formulas and equations in the abstract are not patentable subject matter (MPEP 2106 Patent Subject Matter Eligibility). The following equation as claimed, $ATT_{(x,y,z)} = 10*LOG$ [(energy of reference signal)$_{(x,y,z)}$ / (energy of bone signal) $_{(x,y,z)}$], is not taught by any of the references verbatim. However, Mazess'029 teaches a system wherein the ATT at the at least one point (x,y,z) of the sample is calculated by the processor from the energy of the received ultrasound signal as passed through the bone sample and the energy of a reference ultrasound signal received without the sample positioned between the transducers (Col. 9, Line 5-39). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order compare the characteristics of the waveform in frequency response and attenuation through the subject compared to the standard (without the sample) for analysis (Col. 9, Line 18-25).

Claim 15/12/10/1: Kantorovuch'019 teaches where at least one bone property determined at the at least one point is bone mineral density (BMD) (Col. 2, Line 9-11 & Col. 17, Line 45-50).

Claim 16/15/12/10/1: Formulas and equations in the abstract are not patentable subject matter (MPEP 2106 Patent Subject Matter Eligibility). The following equations

as claimed, BMD = e + f* UV + g * BUA, BMD=a+b* UV+c* BUA+d*UV^2, BMD =u+v* UV +w* ATT, are not taught by any of the references verbatim. However, Kantorovuch'019 teaches the measure of BMD can be determined from broadband ultrasonic attenuation (BUA) (Col. 5, Line 18-27) and ultrasound velocity (Col. 2, Line 9-11 & Col. 17, Line 45-50). While Kantorovuch'019 touches on ultrasound attenuation, the focus of the teachings is measuring ultrasound velocity. Kantorovuch'019 and Mourad'176 fail to mention an ultrasound attenuation number (ATT). ATT represents the energy decay attenuation as a function of material density as defined by the applicant on Page 27, 2nd Paragraph. Mazess'029 goes into detail regarding the applicant defined ATT, although Mazess'029 does not use the term ATT. Mazess'029 states that ultrasound attenuation is dependent on bone mineral density and the integrity being tested (Col. 9, Line 26-54). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order determine the quality of cancellous bone matrix (Col. 9, Line 54-56).

Claim 17/16/15/12/10/1: Constants are not patentable material in the abstract (MPEP 2106 Patent Subject Matter Eligibility) and the following constants are not used verbatim in any of the references. However, Mazess'029 teaches using linear regression constants predetermined by conducting a regression analysis between measurements of BUA on bone specimens and BMD measurements on the bone specimens using conventional analysis (Col. 11, Line 9-16). In addition, Mazess'029 teaches the use of UV (Col. 19, Line 17-49) and ATT (Col. 9, Line 26-54) for determining the BMD. It would have been obvious to one of ordinary skill in the art to

combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order utilize a method that is quick and free of radiation for the evaluation of bone integrity (Col. 19, Line 46-49).

Claim 18/12/10/1: Mourad'176 and Kantorovuch'019 fail to go into details regarding stiffness of bone. Mazess'029 teaches a system wherein the at least one bone property determined at the at least one point is Stiffness (Col. 27, Line 30-40). The applicant defines Stiffness as "From the tissue level regions of bone that experience relatively high stiffness tend more towards cortical bone. Regions of bone experiencing low Stiffness tend to be more trabecular" (Page 3). From the applicant's admission, stiffness is related to the amount of either the cortical or trabecular bone. While Mazess'029 does not explicitly use the word stiffness, Mazess'029 does teach a system capable of measuring both the trabecular and cortical bone and both reading providing distant data about the bone (Col. 27, Line 38-39). Mazess'029 also cites an article by Lees stating "[V]arious studies involving attenuation and speed of sound measurements in both cortical and spongy (cancellous or trabecular) bone....The transit time of an acoustic signal through a bone member therefore are proportional to the bone density" (Col. 2, Line 3-12). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order have a useful parameter in the diagnosis of osteoporosis or as a predictor of possible fracture risk (Col. 2, Line 22-23).

Claim 19/18/12/10/1: Formulas and equations in the abstract are not patentable subject matter (MPEP 2106 Patent Subject Matter Eligibility). The following equations

as claimed, Stiffness = l + m * UV + n * BUA, Stiffness - h + i * UV + j * BUA + k * $(UV)^2$, Stiffness = p + q * UV + r * ATT, are not taught by any of the references verbatim. However, Kantorovuch'019 teaches the measure of broadband ultrasonic attenuation (BUA) (Col. 5, Line 18-27) and ultrasound velocity (Col. 2, Line 9-11 & Col. 17, Line 45-50). While Kantorovuch'019 touches on ultrasound attenuation, the focus of the teachings is measuring ultrasound velocity. Kantorovuch'019 and Mourad'176 fail to mention an ultrasound attenuation number (ATT) and stiffness. ATT represents the energy decay attenuation as a function of material density as defined by the applicant on Page 27, 2nd Paragraph. Mazess'029 goes into detail regarding the applicant defined ATT, although Mazess'029 does not use the term ATT. Mazess'029 states that ultrasound attenuation is dependent on bone mineral density and the integrity being tested (Col. 9, Line 26-54). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order determine the quality of cancellous bone matrix (Col. 9, Line 54-56). In addition, Mazess'029 teaches a system capable of determining stiffness (Col. 27, Line 38-39). Mazess'029 does teach a system capable of measuring both the trabecular and cortical bone and both reading providing distant data about the bone (Col. 27, Line 38-39). Mazess'029 also cites an article by Lees stating "[V]arious studies involving attenuation and speed of sound measurements in both cortical and spongy (cancellous or trabecular) bone....The transit time of an acoustic signal through a bone member therefore are proportional to the bone density" (Col. 2, Line 3-12). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029,

Mourad'176 and Kantorovuch'019 in order have a useful parameter in the diagnosis of osteoporosis or as a predictor of possible fracture risk (Col. 2, Line 22-23).

Claim 20/19/18/12/10/1: Constants are not patentable material in the abstract (MPEP 2106 Patent Subject Matter Eligibility) and the following constants are not used verbatim in any of the references. However, Mazess'029 teaches using linear regression constants predetermined by conducting a regression analysis between measurements of BUA on bone specimens and BMD measurements on the bone specimens using conventional analysis (Col. 11, Line 9-16). In addition, Mazess'029 teaches the use of UV (Col. 19, Line 17-49), stiffness (Col. 27, Line 38-39) and ATT (Col. 9, Line 26-54) for determining the BMD. It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order utilize a method that is quick and free of radiation for the evaluation of bone integrity (Col. 19, Line 46-49).

Claim 21: Kantorovuch'019 teaches a method for determining at least one property of materials (Col. 4, Line 60-64). Kantorovuch'019 fails to teach confocal transducers. However, Mourad'176 teaches a system for using confocal transducers to receive and transmit the ultrasound for determining material properties (Col. 23, Line 20-37). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mourad'176 and Kantorovuch'019 in order to induce an oscillatory radiation force in the target material. The oscillatory radiation force produces an emitted acoustic signal from the targeted material, which relates to the targeted material intrinsic properties (Col. 23, Line 27-33). Mazess'029 teaches positioning a material sample so

that the ultrasonic signal passes through the material sample and such that the point of interest of the material sample lies within the ultrasonic signal (Col. 8, Line 67 – Col. 9 Line 4). Mazess'029 teaches receiving the ultrasonic signal after it passes through the material sample (Col. 5, Line 40-44). Mazess'029 teaches determining at least one ultrasonic parameter for each point in the sample based upon the transmitted and received ultrasonic signals (Col. 5, Line 50-57). Mazess'029 teaches the processor further determining the at least one bone property at each point of the sample based upon the at least one ultrasonic parameter for the point (Col. 5, Line 50-57). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 so that the system can carry out its operations (Col. 6, Line 1-2).

Claim 22/21: Kantorovuch'019 and Mazess'029 fail to teach the confocal point. However, Mourad'176 teaches the confocal point (Figure 4 & Col. 23, Line 51-54). Mourad'176 does not explicitly teaches the confocal point being not greater than approximately 0.5 mm. Although, Mourad'176 teaches that a large number of annular transducers generally provide a greater degree of control and precision of where...the radiation force is focused (Col. 27, Line 12-14). Mourad'176 thus teaches that a confocal point could be not greater than approximately 0.5 mm. It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order to provide a greater degree of control and precision (Col. 27, Line 12-14).

Claim 23/22/21: Kantorovuch'019 and Mazess'029 fail to teach the confocal point. However, Mourad'176 teaches the confocal point (Figure 4 & Col. 23, Line 51-54). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order to induce an oscillatory radiation force in the target tissue. The oscillatory radiation force produces an emitted acoustic signal from the targeted tissue, which relates to the targeted tissues intrinsic properties (Col. 23, Line 27-33). Kantorovuch'019 teaches repositioning the point to a new point of interest in the material sample (Col. 11, Line 21-45). Kantorovuch'019 teaches repeating steps for the new point of interest in the material sample (Col. 11, Line 40-45).

Claim 24/23/22/21: Kantorovuch'019 teaches repeating steps for the new point of interest in the material sample (Col. 11, Line 40-45) but fails to teach the steps in a volume. However, Mazess'029 teaches the array of point of interest comprising a volume (Col. 28, Line 58-63). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order provide the opportunity to use extra data outside the region of interest to ensure that the same region of interest is measure in the patient's heel over a series of measurements made at different times (Col. 28, Line 18-22).

Claim 25/24/23/22/21: Kantorovuch'019 teaches a method wherein scanning a small part of the body smaller than 1 mm (Claim 95). Kantorovuch'019 teaches a functional equivalent method capable of the measurements claimed by the applicant. Kantorovuch'019 fails to teach the points in the array. However, However, Mazess'029

teaches the array of point of interest comprising a volume (Col. 28, Line 58-63). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order provide the opportunity to use extra data outside the region of interest to ensure that the same region of interest is measure in the patient's heel over a series of measurements made at different times (Col. 28, Line 18-22).

Claim 26/22: Kantorovuch'019 teaches the determining the ultrasonic velocity (UV) (Abstract) and a measure of ultrasonic attenuation (UA) for the point of interest (Col. 5, Line 18-27).

Claim 27/22: Kantorovuch'019 teaches determining the at least one material property at the point of interest of the sample comprises determining at least one of elasticity, density, shear strength and tensile strength (Col. 21, Line 45-47).

Claim 28/22: Kantorovuch'019 teaches the material sample comprises a bone sample (Col. 3, Line 54-57).

Claim 30: Kantorovuch'019 teaches a method determining the broadband ultrasound attenuation (BUA) of an ultrasound signal passing through the point of the sample (Col. 5, Line 18-27). Mourad'176 and Kantorovuch'019 fail to go into details regarding stiffness of bone. Mazess'029 teaches a system wherein the at least one bone property determined at the at least one point is Stiffness (Col. 27, Line 30-40). The applicant defines Stiffness as "From the tissue level regions of bone that experience relatively high stiffness tend more towards cortical bone. Regions of bone experiencing low Stiffness tend to be more trabecular" (Page 3). From the applicant's

admission, stiffness is related to the amount of either the cortical or trabecular bone. While Mazess'029 does not explicitly use the word stiffness, Mazess'029 does teach a system capable of measuring both the trabecular and cortical bone and both reading providing distant data about the bone (Col. 27, Line 38-39). Mazess'029 also cites an article by Lees stating "[V]arious studies involving attenuation and speed of sound measurements in both cortical and spongy (cancellous or trabecular) bone....The transit time of an acoustic signal through a bone member therefore are proportional to the bone density" (Col. 2, Line 3-12). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 in order have a useful parameter in the diagnosis of osteoporosis or as a predictor of possible fracture risk (Col. 2, Line 22-23). Formulas and equations in the abstract are not patentable subject matter (MPEP 2106 Patent Subject Matter Eligibility). The following equation as claimed, Bone Quality Index = 0.7 BUA/β + 0.3 Stiffness/τ, is not taught by any of the references verbatim. However, Mazess'029 teaches developing a numerical value (index value) indicative of the integrity and mineral density of a bone (Col. 19, Line 17-30). Mazess'029 teaches using BUA (Col. 19, Line 39-49) and stiffness (Col. 27, Line 38-39) to evaluate bone quality (Col. 19, Line 17-30). It would have been obvious to one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 for reproducible accuracy (Col. 19, Line 31-39). Mazess'029 fails to teach normalization. However, Kantorovuch'019 teaches normalization for use in calculations (Col. 18, Line 1-33). It would have been obvious to

one of ordinary skill in the art to combine the teachings of Mazess'029, Mourad'176 and Kantorovuch'019 for determining the constant for human bones (Col. 18, Line 10-13).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Chiabrera, Alessandro et al. Ultrasonic bone assessment method and apparatus. US 5785656 A.

B. Faulker, K enneth G. et al. Bone densitometer providing assessment of absolute fracture risk. US 6740041 B2.

C. Hoff, Lars et al. Ultrasound measurement techniques for bone analysis. US 6899680 B2

D. Ohtomo, Naoki. Bone assessment apparatus. US 6095979 A.

E. Pratt, Jr., George W. Method for determining in vivo, bone strength. US RE32782 E.

F. Sarvazyan; Armen P. et al. Method and device for multi-parametric ultrasonic assessment of bone conditions. US 6468215 B1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

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